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Bob Naviaux

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File declaration to bring
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TO: Ms. JEANINE GOLDBERG
USPTO Art Unit 1634

FAX# (703) 746-5149
December 9, 2003

FROM: Khue Nguyen, Ph.D. and
H-Mai Nguyen, Ph.D.

RE: Response draft on the issue of new matter, Application #09,938,013

This is an initial draft to facilitate our discussion over the phone when we call you. The following is to explain that there was no new matter brought up, which relates to your question of what portions of exons 7 and 8, i.e. what constitutes probes 1 and 2; probe 3 is also addressed.

In the field of molecular biology, when forward primer's and reverse primer's positions from which number to which number of nucleotides are specified, it refers to what portions of the gene is to be used.

Probe 1:

The specified positions of the oligonucleotide (g), forward primer position from 869-889 and the oligonucleotide (h), reverse primer position from 901-921 of the exon 7 of the SMN gene, refer to the portions of exon 7 of the SMN gene; therefore, based on such information, persons in the field of molecular biology would know exactly that the sequence fragment from 869-921 of exon 7 of the SMN gene is to be amplified in order to construct probe 1.

Probe 2:

The specified positions of the oligonucleotide (i), forward primer position from 922-941 and the oligonucleotide (d), reverse primer position from 957-976 of the exon 8 of the SMN gene, refer to the portions of exon 8 of the SMN gene; therefore, based on such information, persons in the field of molecular biology would know exactly that the sequence fragment from 922-976 of the exon 8 of the SMN gene is to be amplified in order to construct probe 2.

Probe 3:

The specified positions of the oligonucleotide (e), forward primer position from 672-690 and the oligonucleotide (f), reverse primer position from 705-723 of the HUMEF1AB gene, refer to the portions of HUMEF1AB gene; therefore, based on such information, persons in the field of molecular biology would know exactly that the sequence fragment from 672-723 of HUMEF1AB gene is to be amplified in order to construct probe 3.

(See pages 5, 6, 8 and 9 of the application).

As the whole sequences of the exons 7 and 8 of the SMN gene are well known (see page 158 of the Reference #16 in the application — Lefebvre et al. Cell 1995, Vol.80, pp. 155-165), it is not necessary to specify the sequences of the probes 1 and 2 in the

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application. The whole sequence of HUMEF1AB gene is also well known in Ann et al., 1988, in Reference #20 in the application; therefore, it is not necessary to specify the sequence of probe 3.

In conclusion, there is no new matter introduced in the disclosure.